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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/827,688	04/06/2001	Frank M. Orson	P01949US1	5045

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EXAMINER

NGUYEN, QUANG

ART UNIT

PAPER NUMBER

1636

DATE MAILED: 07/01/2002

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/827,688

Applicant(s)

ORSON ET AL.

Examiner

Quang Nguyen, Ph.D

Art Unit

1636

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-57 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☐ Claim(s) ____ is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☒ Claim(s) 1-57 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) ____.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). ____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

DETAILED ACTION

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1-42, drawn to a composition comprising an expression vector bound to an aggregated protein-polycationic polymer conjugate; methods of inducing an immune response in an organism comprising the step of administering to an organism the same composition; a method of introducing genes into a cell comprising the steps of forming a DNA particle comprising an expression vector bound to an aggregated protein-polymer conjugate and incubating the cells with the DNA particle under conditions wherein the cell take in the DNA particle; a method for producing a DNA vaccine comprising the step of incubating an expression vector with an aggregated protein-polycationic polymer conjugate, and a method of treating a condition in an organism using the same DNA vaccine, classified in class 514, subclass 44; class 435, subclass 320.1.
- II. Claims 43-57, drawn to a composition comprising an expression vector bound to a protein-polycationic polymer suspension, and a method of inducing an immune response in an organism using the same, classified in class 435, subclass 320.1; class 514, subclass 44.

The inventions are distinct, each from the other because of the following reasons:

The methods of Groups I and II differ one from the other because they require different starting materials. While the composition of Group II comprises an expression vector bound to a protein-polycationic polymer suspension, different in chemical and physical composition from the composition of Group I comprising an expression vector bound to an aggregated protein polycationic polymer conjugate.

Because these inventions are distinct for the reasons given above and that the prior art teaching the composition in Groups I would not necessarily anticipate the composition in Group II, it would be unduly burdensome for the examiner to search and/or consider the patentability of all the inventions within a single application. Therefore, restriction for examination purposes as indicated is proper.

Species Restriction:

Should Applicants elect the invention of Group I or Group II, the elected invention contains the following patentably distinct species:

Claims 1-4, 6-15, 17-27, 43-46 and 48-53 are generic to a plurality of disclosed patentably distinct species comprising:

A polynucleotide sequence encoding an antigen selected from the group of genomes or genes associated with: (a) infectious disease, (b) cancer, and (c) autoimmune disease.

Applicant is required under 35 U.S.C. 121 to elect a specifically named species as indicated above.

Additionally, should Applicants elect species (c), claims 1-27 and 43-53 are generic to a plurality of disclosed patentably distinct species comprising:

A specifically named autoimmune disease as listed in the Markush group of claim 5 or claim 16 or claim 47.

Applicant is required under 35 U.S.C. 121 to elect a specifically named species as indicated above.

Claims 1-3, 5-14, 16-27, 43-45 and 47-53 are generic to a plurality of disclosed patentably distinct species comprising:

A specifically named polynucleotide sequence encoding an antigen selected from pathogenic genomes of: (i) virus, (ii) bacterium, (iii) fungus, and (iv) protozoa.

Applicant is required under 35 U.S.C. 121 to elect a specifically named species as indicated above.

Additionally, should Applicants elect species (i) virus, claims 1-27 and 43-53 are generic to a plurality of disclosed patentably distinct species comprising:

A specifically named viral genomes as listed in the Markush group of claim 4 or claim 15 or claim 46.

Applicant is required under 35 U.S.C. 121 to elect a specifically named species as indicated above.

Should Applicants elect the invention of Group I, the elected invention contains the following patentably distinct species:

Claims 23-25 and 32-36 are generic to a plurality of disclosed patentably distinct species comprising:

A specifically named mucosal surface as listed in the Markush group of claim 25 or claim 36.

Applicant is required under 35 U.S.C. 121 to elect a specifically named species as indicated above.

Claims 23 and 26-27 are generic to a plurality of disclosed patentably distinct species comprising:

A specifically named parenteral administration as listed in the Markush group of claim 27.

Applicant is required under 35 U.S.C. 121 to elect a specifically named species as indicated above.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a diligently-filed petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17 (h).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Quang Nguyen, Ph.D., whose telephone number is (703) 308-8339.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's mentor, Dave Nguyen, may be reached at (703) 305-2024, or SPE, Irem Yucel, Ph.D., at (703) 305-1998.

Any inquiry of a general nature or relating to the status of this application should be directed to Patent Analyst, Tracey Johnson, whose telephone number is (703) 305-2982.

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To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Group Art Unit 1636.

Quang Nguyen, Ph.D.



DAVE T. NGUYEN
PRIMARY EXAMINER